

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P083PCT		FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/009096	International filing date (day/month/year) 28.06.2004	Priority date (day/month/year) 30.06.2003	
International Patent Classification (IPC) or national classification and IPC			
Applicant NIHON PHARMACEUTICAL CO., LTD.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/009096

Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
 - ☐ international search (Rule 12.3 and 23.1(b))
 - ☐ publication of the international application (Rule 12.4)
 - ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☒ the international application as originally filed/furnished
 - ☐ the description:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____
 - ☐ the claims:
 - nos. _____ as originally filed/furnished
 - nos.* _____ as amended (together with any statement) under Article 19
 - nos.* _____ received by this Authority on _____
 - nos.* _____ received by this Authority on _____
 - ☐ the drawings:
 - sheets _____ as originally filed/furnished
 - sheets* _____ received by this Authority on _____
 - sheets* _____ received by this Authority on _____
 - ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-7</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims <u>1-7</u>	YES
	Claims _____	NO
Industrial applicability (IA)	Claims <u>1-7</u>	YES
	Claims _____	NO

2. Citations and explanations (Rule 70.7)

The present written opinion was drafted on the basis of disclosures from the following documents, which are cited in the international search report.

Document 1: T. ASAO et al., Gastrointest. Endosc., 2001, Vol. 53, No. 2, pages 172 to 177

Document 2: M. MORITA et al., Natural Med., Vol. 52, No. 1, pages 22 to 31

Document 3: Naoki HIKI et al., Dai 10 Kai Clinical Video Forum (CVF) Program Shouroku-shuu, 2002, page 73

Document 4: JP 6-56623 A (Kao Corp.)

Document 5: WO 92/06947 A1 (Pulitzer Italiana S. R. L.)

Claims 1 to 7

Documents 1 to 3 indicate that peppermint oil and L-menthol suppress peristaltic movement, and are thus useful as anticonvulsant agents. Herein, a comparison of the invention that is set forth in claims 1 to 7 and the inventions that are disclosed in documents 1 to 3 shows that the former invention differs from the latter inventions in that it comprises an antifoaming agent and has an average particle diameter of less than 100 nm.

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

Meanwhile, document 4 makes disclosures in relation to an aqueous composition that comprises a dimethylpolysiloxane as an antifoaming agent. However, the composition in question is primarily used in cosmetic products, and document 4 does not include any specific disclosures in relation to the average particle diameter thereof; consequently, it cannot be said to have been easy to conceive of the invention set forth in claims 1 to 7 in the light of the disclosures in question, even for a person skilled in the art.

In addition, document 5 discloses preparations which exhibit actions similar to those disclosed in documents 1 to 3; however, the active components thereof are L-menthol derivatives other than L-menthol itself, and thus said active components are different from the active components of the present application.

Therefore, the invention that is set forth in claims 1 to 7 involves an inventive step in relation to the disclosures of documents 1 to 5.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 03/097026 A1 [EY]	27.11.2003	20.05.2002	22.05.2002 27.12.2002
WO 03/097027 A1 [EY]	27.11.2003	20.05.2002	22.05.2002 27.12.2002
JP 2003-292450 A [EY]	15.10.2003	29.08.2002	01.02.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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